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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,320	05/29/2002	Adriano Cocola	70479	1540

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EXAMINER
PAIK, STEVE S

ART UNIT	PAPER NUMBER
2876	9

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,320	COCOLA ET AL.	
	Examin r	Art Unit	
	Steven S. Paik	2876	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

3. The disclosure is objected to because of the following informalities: The applicant is encouraged to insert a paragraph including a continuing data such as a 371 of PCT/IT00/00359 filed on September 12, 2000 immediately after the title of the invention. Appropriate correction is required.

Response to Amendment

4. Receipt is acknowledged of the Preliminary Amendment filed May 29, 2002.

Claim Objections

5. Claim 1 is objected to because of the following informalities: the phrase, "its own identification code" in line 3 appears to be inappropriate. The examiner respectfully suggests amending the phrase as – a unique identification code of said container – and replacing the bullet points "•" for each recited steps with – (a), (b), (c), and (d) --. Appropriate correction is required.

6. Claim 2 is objected to because of the following informalities: the word, "feast" in line 2 appears to be – least --. The examiner also suggests replacing the bullet points "•" for each recited steps with – (a), (b), (c), and (d) --. Appropriate correction is required.

7. Claim 10 is objected to because of the following informalities: it is respectfully suggested to replace the bullet points "•" for each recited steps with – (a), (b), (c), and (d) --. Appropriate correction is required.

8. Claim 13 is objected to because of the following informalities: the word, "it" in line 1 appears to be inappropriate. The examiner respectfully suggests replacing the word with – said container --. Appropriate correction is required.

9. Claim 16 is objected to because of the following informalities: the word, "it" in line 1 appears to be inappropriate. The examiner respectfully suggests replacing the word with – said container --. Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 5, 6, 8-13, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaffin, III et al. (US, 831,006, cited by the applicant).

Re claim 1, Chaffin, III et al. disclose a patient-specimen identification system (Fig. 1) and method for data management in an analytical laboratory, comprising the steps of:

providing a plurality of containers (sample container 15/sub-sample containers 23) for laboratory analysis of biological specimens, each container being associated with its own identification code (16 or 24);

associating a patient code (12) with a patient to be subjected to analysis;

for each container used for said patient, generating in a data processing system (logic 32 and memory 13) a combination (at steps 17, 20, and 21) of said patient code (12) and said identification code (16) of the corresponding container;

carrying out, by means of at least one analyzer (27), at least one analysis on the container or containers used for said patient, the analyzer entering the results of said analysis, combined (at memory 13) with the identification code of the container (15) or containers (23), into the data processing system (logic 32 and memory 13).

Re claim 2, Chaffin, III et al. disclose the method as recited in rejected claim 1 stated above, further comprising the steps of:

generating a patient code (col. 3, ll. 1-10) for at least one patient on whom at least one analysis is to be carried out and storing said patient code in a data processing system (patient information is stored at memory 13 of a data processing system comprising logic 32 and memory 13);

placing a biological specimen from said patient in said at least one container (col. 3, ll. 17-23);

carrying out at least one analysis of said specimen in at least one analyzer (27), the analyzer reading the identification code of said container (via reader #3) and entering into said data processing system the results of the analysis (test results) combined with the identification code (16 or 24) of said container;

using said data processing system (logic 32 and memory 13) to associate the results of the analysis or analyses with the patient code (12), and then with the patient identified by the patient code, by means of the combination of the patient code with the identification code.

Re claim 3, Chaffin, III et al. disclose the method as recited in rejected claim 1 stated above, where said identification code (16 or 24) is placed on the corresponding container in a machine readable format (col. 3, ll. 23-30 and ll. 61-64).

Re claim 5, Chaffin, III et al. disclose the method as recited in rejected claim 1 stated above, in which the patient code (12) is placed on a medium in a machine-readable format (col. 3, ll. 1-10).

Re claim 6, Chaffin, III et al. disclose the method as recited in rejected claim 3 stated above, in which the combination of the patient code (12) with the identification code (16 or 24) is generated by the sequential reading by an automatic reading instrument (reader #1-3) of the patient code and the identification code, or vice versa.

Re claim 8, Chaffin, III et al. disclose the method as recited in rejected claim 1 stated above, in which said patient code (12) is generated by a central computer of said data processing system; the combination of the patient code (12) with the identification code (16 or 24) is carried out by means of a unit (13) of said data processing system other than said central computer; and the result of the analysis, associated with the patient code is sent to said central computer (col. 4, ll. 45-53).

Re claim 9, Chaffin, III et al. disclose the method as recited in rejected claim 1 stated above, in which said patient code (12) is generated by a central computer of said data processing system; the combination of the patient code (12) with the identification code (16 or 24) is carried out by means of a unit (13) of said data processing system other than said central computer; and the result of the analysis, associated with the patient code is sent to said central computer (col. 4, ll. 45-53), the central computer being programmed to associated with the result of the analysis

the data relating to the patient to whom said results relates (the logic 32 may comprises any digital computers or any dedicated logic/memory unit. In a computer system having a network, which is in common in a laboratory or hospital system, it is inherent to designate a computer as a main or a central computer or database server to perform data management.).

Re claim 10, Chaffin, III et al. disclose a data managing system (Fig. 1) for data management in an analytical laboratory comprising, in combination,

a central electronic computer (col. 4, ll. 45-53), for acquiring the data on patients (10) on whose biological specimens (such as blood) the analyses are to be carried out, and for generating a patient code (12) for each patient acquired;

means for acquiring (readers #1-3) an identification code (16 or 24) associated with each container (15 or 23) of a plurality of containers for laboratory analysis of biological specimens;

means for combining (memory 13) each of said acquired identification codes with a corresponding patient code;

at least one analyzer (27) with means for reading identification code (via readers #2 and #3) associated with the containers which are placed in it, said analyzer carrying out at least one analysis on a biological specimen contained in the containers placed in it and supplying to said electronic computer (logic 32) the results of the analyses carried out, combined with data capable of associating said result (test results) with the patient (10) whom the biological specimen belongs.

Re claim 11, Chaffin, III et al. disclose the system as recited in rejected claim 10 stated above, further comprising means for receiving (memory 13) from said at least one analyzer (27) the result of said at least one analysis (test results) combined with the identification code (16 or

24) of the container in which the analyzed biological specimen is placed, said means being programmed to associate said result with the patient code (12) relating to the identification code combined with the result of the analysis, to send the result analysis combined with the patient code to and central electronic computer (logic 32; col. 4, ll. 45-53).

Re claim 12, Chaffin, III et al. disclose the system as recited in rejected claim 10 stated above, in which the result of the analysis, combined with the identification code (16 or 24) of the corresponding container (15 or 23), is sent to said central computer (via memory 13), the central computer (logic 32; col. 4, ll. 45-53), the central computer being programmed to associate, by means of the combination of the patient code (12) with the identification code, each identification code- and consequently the result of the analysis – with the patient code of the patient whose biological specimen is contained in the container identified by said identification code.

Re claim 13, Chaffin, III et al. disclose a container for laboratory analysis of biological specimens, characterized in that it is provided with a unique machine-readable identification code. Column 1, lines 63-67 disclose that machine-readable labels are attached to a patient and to each sample container. Furthermore, the machine-readable labels in the reference comprise a fourteen-hole pattern representing four octal digits, two label identification bits, and two parity bits. Chaffin, III et al. also suggest that other type of label or coding system may be used.

Re claim 17, Chaffin, III et al. disclose a set of containers for laboratory analysis of biological specimens, characterized in that each of said containers has a unique identification code which is different from the identification codes of the other containers of said set and is machine readable. Column 2, lines 4-7 teaches a situation when portions of sample are

transferred to sub-sample containers (a set of containers). Each sub-sample containers (23) has a unique sub-sample container label (24) which are also machine readable by a reader (25).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 4, 7, 14, 15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaffin, III et al. (US 3,831,006) in view of Knepple et al. (WO 99/41014, Abstract).

Re claims 4, 7, 14, 15, 18, and 19, Chaffin, III et al. disclose a sample container (15) or sub-sample containers (23) having a unique machine-readable label (16 or 24) for each of the sample container or sub-sample containers. The labels are machine-readable labels for a patient-specimen identification system. The coding on the labels comprises a fourteen-hole pattern representing four octal digits, two label identification bits, and two parity bits. Furthermore, Chaffin, III et al. teach or suggest that any other type of label or coding system may be used with the patient-specimen identification system.

However, Chaffin, III et al. fail to specifically disclose or suggest the limitations concerning an identification code being applied on said container during the production of the container, and the identification code being a barcode.

Knepple et al. disclose a sample containers (10) used in an analysis device including a machine-readable identification label (12, barcode, page 6, line 17) applied during production

(10a in the Figure) of the sample container. Since the unique identification code (barcode) is applied during production process, a lab technician does not have to print and affix a separate machine-readable label on a sample container. This process obviously saves time and a eliminates a chance of erroneously applying a machine-readable label to a wrong sample container.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention was made to incorporate the method of applying a unique machine-readable identification code (12 barcode) to a sample container (10) during production (10a), as taught by Knepple et al. to the patient-specimen identification system of Chaffin, III et al. for the purpose of simplifying the steps of analysis in a laboratory by eliminating the process of generating a unique machine-readable label for each sample container and affixing the label to a right sample container. Furthermore, such modification of using a sample container with a unique machine-readable code label applied during production obviously prevents a lab technician from erroneously mixing the label and the sample container.

14. Claims 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaffin, III et al. (US 3,831,006) in view of Carr et al. (US 5,888,825).

Re claims 16 and 20, Chaffin, III et al. disclose a sample container (15) or sub-sample containers (23) having a unique machine-readable label (16 or 24) for each of the sample container or sub-sample containers. The labels are machine-readable labels for a patient-specimen identification system. The coding on the labels comprises a fourteen-hole pattern representing four octal digits, two label identification bits, and two parity bits. Furthermore,

Chaffin, III et al. teach or suggest that any other type of label or coding system may be used with the patient-specimen identification system.

However, Chaffin, III et al. do not disclose or suggest the feature concerning means for determining an expiry date.

Carr et al. disclose a sample bottle (602 in Fig. 3) typically contains a blood or other sample to be monitored for microorganism content. The bottle includes a unique barcode (616) comprising an individual number, plus batch code and expiry data information. As appreciated by an artisan of ordinary skill in the art, a barcode may contain any encoded information in accordance with a user's need. For example, a barcode used in a library system mostly would contain information about a book, a publisher, and circulation data, etc. Another barcode used in a grocery store obviously contains information about a product or good, price, and promotions, etc. Furthermore, it is well-known that a biological sample in a laboratory would have a predetermined expiration date to prevent the sample from being contaminated after a period of time.

In view of Carr et al. it would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ a unique barcode having an individual number, plus batch code, and expiry data information in addition to the patient-specimen identification system of Chaffin, III et al. for the purpose of getting accurate analysis report from a sample without having to concern about the state of the sample. Furthermore, deciding what to be included in a barcode varies by the need and application of the barcode system. Hence, such modification of employing a barcode having an expiry data to the teachings of Chaffin, III et al.

would have been an obvious matter of design variation, well within the ordinary skill in the art, and therefore an obvious expedient.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Marquiss discloses a system for identifying labware and sample containers having a machine-readable unique identification label.

Igarashi et al. disclose a system for processing specimen contained in a container with a unique specimen identification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven S. Paik whose telephone number is 703-308-6190. The examiner can normally be reached on Mon - Fri (5:30am-2:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on 703-305-3503. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6893 for regular communications and 703-308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0530.

Steven Paik

Steven S. Paik
Examiner
Art Unit 2876

ssp
August 8, 2003